REMARKS

Claims 21, 28-33 and 35-49 were pending and under consideration. With this amendment, Claims 31, 38-45 and 48-49 are canceled without prejudice. Claim 21 has been amended. New Claims 50-53 have been added. After entry of the instant amendment, Claims 21, 28-30, 32-33, 35-37, 46-47 and 50-53 are pending and under consideration. A version with markings to show changes made is attached at Exhibit A. For convenience, a clean copy of the pending claims after entry of the instant amendment is attached at Exhibit B.

I. THE AMENDMENT TO THE CLAIM

Claim 21 has been amended to recite, in relevant part, a method for identifying the presence of cancerous cells in a human sample using a pair of primers, wherein said pair of primers consists of a first primer which hybridizes within exon 8 of the hTERT gene and a second primer which hybridizes upstream of exon 7 or downstream of exon 8 of the hTERT gene. Support for amended Claim 21 can be found, for example, in Claim 21 as originally filed. Support for amended Claim 21 can also be found, for example, in the specification at page 15, line 29 to page 16, line 20, as acknowledged by the PTO, in the final Office Action mailed December 12, 2002, page 2.

As the amendment is fully supported by the specification and claims as originally filed, it does not constitute new matter. Applicants believe amended Claim 21 is in better form for consideration on appeal and reduces the number of issues for appeal. Applicants hereby request entry of the amendments into the record.

II. THE NEW CLAIMS

New Claim 50 recites a method for identifying the presence of cancerous cells in a human sample wherein said method comprises: (a) determining the quantity of hTERT mRNA comprising β-region coding sequence in said sample and in a control sample of non cancerous cells by: (1) amplifying the β-region of the hTERT gene and said control sample; (2) measuring the generation of amplification products; (3) determining the quantity of hTERT mRNA comprising β-region coding sequence in said sample from the results obtained in step (2); and

(b) identifying the presence of cancerous cells in said sample if the quantity of hTERT mRNA comprising β-region coding sequence in said sample is greater than the quantity of hTERT mRNA comprising β-region coding sequence in said control sample. Support for new Claim 50 can be found in the specification, for example, at page 21, lines 4 to 8 and page 26, lines 29 to 33.

New Claim 51 recites the method of Claim 50, wherein the amplification is carried out with a pair of primers, said pair of primers consists of a first primer which hybridizes upstream of exon 8 of the hTERT gene and a second primer which hybridizes downstream of exon 8 of the hTERT gene. New Claim 52 recites the method of Claim 51, wherein said first primer hybridizes within exon 6 of the hTERT gene and said second primer hybridizes within exon 9 of the hTERT gene. New Claim 53 recites the method of Claim 52, wherein said first primer is SYC1076 (SEQ ID NO:2) and said second primer is SYC1078 (SEQ ID NO:3). Support for new Claims 51-53 can be found in the specification, for example, at page 20, line 14 to page 21, line 8.

Applicants have canceled eleven claims and present four new claims. In addition, Applicants believe the new claims are in condition for allowance and therefore reduce the number of issues for appeal. Applicants hereby respectfully request entry of Claims 50-53 into the record.

III. 35 U.S.C. §112, FIRST PARAGRAPH

Claims 21, 28-33 and 35-49 stand rejected allegedly as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The PTO states that the specification allegedly does not describe or discuss a second primer that "hybridizes within, upstream or downstream of exon 8 of the hTERT" (Office Action mailed December 9, 2002, page 2).

Applicants submit that Claims 38-45 and 48-49 are fully supported by the specification, however merely to place the claims in condition for allowance, Applicants have canceled Claims 38-45 and 48-49 without prejudice. Therefore the rejection of Claims 38-45 and 48-49 is rendered moot. Claim 21 has been amended to recite, in relevant part, a method for identifying the presence of cancerous cells in a human sample using a pair of primers,

wherein said pair of primers consists of a first primer which hybridizes within exon 8 of the hTERT gene and a second primer which hybridizes upstream of exon 7 or downstream of exon 8 of the hTERT gene. Support for amended Claim 21 can be found, for example, in Claim 21 as originally filed. Support for amended Claim 21 can also be found, for example, in the specification at page 15, line 29 to page 16, line 20, as acknowledged by the PTO, in the final Office Action mailed December 12, 2002, page 2.

New Claims 50-53 are fully supported by the specification, for example, at page 20, line 14 to page 23, line 22 and page 26, lines 29 to 33 wherein methods comprising amplification of a nucleotide product encompassing the β-region from the full length hTERT mRNA sequence is described. For instance, Example 2 describes methods for identifying a nucleotide product encompassing the β-region from the full length hTERT mRNA sequence comprising, amplifying the β-region. Methods comprising amplifying a nucleotide product encompassing the β-region from the full length hTERT mRNA sequence are also described in Example 4 at page 26, lines 29 to 33.

Applicants submit that Claims 21, 28-30, 32-33, 35-37, 46-47 and 50-53 are fully supported by the specification and do not introduce new matter. Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

IV. 35 U.S.C. §103

Claims 38-45 and 48-49 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over Kilian (Human Molecular Genetics, 2011-2019) in view of Nakamura (Genbank Accession Number AF015950) in further view of Stratagene Catalog (1988). Applicants respectfully disagree and submit that Claims 38-45 and 48-49 are not obvious. However, merely to expedite prosecution Applicants hereby cancel Claims 38-45 and 48-49 without prejudice rendering rejection of these claims moot. Applicants respectfully request that the rejection under 35 U.S.C. §103 be withdrawn.

CONCLUSION

Applicants submit that Claims 21, 28-30, 32-33, 35-37, 46-47 and 50-53 satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same and passage of Claims 21, 28-30, 32-33, 35-37, 46-47 and 50-53 to issuance is therefore kindly solicited.

No fees in addition to the Notice of Appeal fee are believed due in connection with this response. However, the Commissioner is authorized to charge all required fees, fees under 37 CFR § 1.17 and all required extension of time fees, or credit any overpayment, to Pennie & Edmonds LLP U.S. Deposit Account No. 16-1150 (Order No. 1803-298-999).

Respectfully submitted,

Date: January 21, 2003

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EXHIBIT A

Claim Amendment: Version with Markings to Show Changes Made

21. (Thrice amended) A method for identifying the presence of cancerous cells in a human sample wherein said method comprises:

(a) determining the quantity of hTERT mRNA comprising β-region coding sequence in said sample and in a control sample of non cancerous cells by:

(1) contacting RNA from said sample and said control sample with a pair of primers, wherein said pair of primers consists of a first primer which hybridizes within exon 8 of the hTERT gene and a second primer which hybridizes [within,] upstream of exon 7 or downstream of exon 8 of the hTERT gene;

(2) amplifying the nucleic acid sequence;

(3) measuring the generation of amplification products;

(4) determining the quantity of hTERT mRNA comprising β-region coding sequence in said sample from the results obtained in step (3); and

(b) identifying the presence of cancerous cells in said sample if the quantity of hTERT mRNA comprising β-region coding sequence in said sample is greater than the quantity of hTERT mRNA comprising β-region coding sequence in said control sample.